



THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Bach, et al.
Serial No.: 08/986,568
Filed: December 5, 1997
For: Method for Treating Spontaneous Auto-Immune Disease in Mammals
Group: 1644

Commissioner for Patents
Box 1450
Alexandria, VA 22313-1450

DECLARATION UNDER 37CFR1.132

I, Louis Vaickus, hereby declare as follows:

1. My curriculum vitae is attached hereto as Exhibit A.
2. The work performed in Paragraphs 3 through 9 was performed by me or those acting under my direction and on my behalf.
3. A cohort, also referred to herein as "Cohort 1," of four human patients suffering from psoriasis was selected for participation in a clinical trial in which such patients would be given 1 mg of TRX4 antibody for the treatment of psoriasis. The patients were from 31 to 51 years of age, and other than the diagnosis of psoriasis, the patients generally were in good health. TRX4 is a non-mitogenic antibody which recognizes CD3.
4. The patients had baseline Psoriasis Area Severity Index (PASI) scores ranging from 12.2 to 27.0 at baseline. None of the patients had received any systemic agents for psoriasis treatment or any potent immunosuppressive agents within 4 weeks prior to receiving TRX4, and no such agents were used for at least 8 weeks after receiving TRX4.

5. Each of the 4 patients was given 1 mg of TRX4 by intravenous infusion over a period of one hour.

6. Immediately after the administration of the TRX4, it was observed that the absolute lymphocyte counts for all individuals decreased. The decrease was observed just after completion of the one-hour infusion of TRX4, and was most prominent between days 1 and 2, and recovery, i.e., an increase of the lymphocyte counts, began on day 3. The lymphocyte counts returned to baseline by day 6.

7. Modulation of the T-cell receptor, or TCR, as detected by staining with an antibody to TCR, was observed most profoundly immediately after the administration of TRX4, with full recovery of the TCR complex on the cell surface within 6 days after dosing.

8. In the patients that were given 1 mg of TRX4, serum levels of TRX4 were detected in the blood immediately after completion of the administration of TRX4, and for up to one hour post-administration.

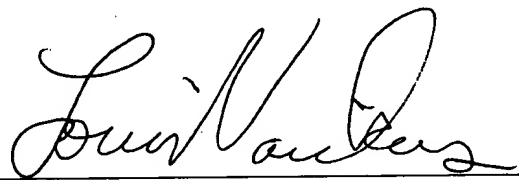
9. Although TRX4 was detected in patient serum for only 1 hour after administration, the patients had reduced lymphocyte counts for only 6 days, and modulation of the T-cell receptor occurred in the patients for only 6 days, all patients of Cohort 1, that were given 1 mg of TRX4, showed decreases in their PASI scores from baseline that were durable at least to 8 weeks after administration. At 8 weeks after administration of TRX4, the patients had decreases in their PASI scores of 37.4%, 45.9%, 48.2%, and 50.6% from baseline, for an average reduction in PASI score from baseline of 45.5%.

10. The above results show that a single administration of the non-mitogenic anti-CD3 antibody TRX4 caused a durable remission of psoriasis for a period of at least 8 weeks, although

TRX4 was not detected in patient serum after 4 hours post-administration, and lymphocyte counts had returned to baseline within 6 days of administration.

11. I hereby declare that all statements made herein are true, and all statements made on information and belief are believed to be true, and further that all statements were made with the knowledge that any willful false statements and the like so made are punishable by fine, or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the above-identified application or any patent issuing thereon.

Date: *March 22, 2005*



LOUIS VAICKUS

#251047 v1

March 15, 2005

CURRICULUM VITAE

LOUIS VAICKUS MD, FACP

Current Title/Position:

Chief Medical Officer
TolerRx Inc.
300 Technology Square
Cambridge, MA 02139
Tel: 617-452-1345
Mobile: 857-919-2493
Fax: 617-354-8300
Email: lvaickus@tolerRx.com

Home Address:

22 Franklin Rogers Rd
Hingham, MA 02043
Phone: 781-740-9028

CURRENT RESPONSIBILITIES

Clinical Development and Medical Affairs: Supervision of all clinical operations and development activities involving two monoclonal antibodies. The scope of this oversight ranges from pre-IND planning and submission to design of Phase I-III trials. These responsibilities include a large retrospective database collection, construction, and analysis from an investigator-initiated trial in Europe that is intended to support US IND indications.

Preclinical Development: Supervision of all preclinical IND enabling and active IND support studies including assay methodology, tech transfer, *in vivo* non-human animal studies (murine to primate), and generation of products to qualify *in vitro* assays.

Regulatory Affairs/Quality Assurance: Supervision of all FDA communications including telecons, face-to-face meetings, identification and oversight of consultants, and pre-IND to BLA submission. The scope of this responsibility includes supervision of GXP (GLP, GMP, GCP) activities within the company.

Executive Leadership: Senior administrative functions including overall company strategy, board of directors updates and interactions, business development including co-development deals and M&A activities, and medical/clinical representation on discovery project teams.

EDUCATION

| | Degree/Position | Institute |
|---------|-----------------------|---|
| 1970-74 | -- | Loyola University, Chicago, IL |
| 1974-77 | MD | Loyola University, Medical Center, Maywood, IL |
| 1977-79 | Immunology Fellowship | Mayo Clinic, Rochester, MN |

March 15, 2005

| | | |
|---------|---|--|
| 1979-82 | Internship and Residency in Internal Medicine | Mayo Clinic, Rochester, MN |
| 1982-83 | Hematology Fellowship | Mayo Clinic, Rochester, MN |
| 1983-85 | Heme/Onc Fellowship | Stanford University Medical Center, Stanford, CA |

BOARD CERTIFICATIONS

| | |
|--|-----------------|
| 1980 - National Board of Medical Examiners | (#188584) |
| 1982 - Internal Medicine | (ABIM # 089560) |
| 1984 - Hematology and Hematologic Malignancies | (ABIM # 089560) |
| 1993 - Medical Oncology | (ABIM # 089560) |

MEDICAL LICENSURE

| <u>State</u> | <u>Perm/Temp</u> | <u>Number</u> | <u>Renewal Date</u> |
|---------------|------------------|---------------|---------------------|
| Massachusetts | (pending) | | |
| New York | Permanent | 176571 | 05/31/03 |
| Iowa | (Inactive) | -- | -- |
| California | (Inactive) | -- | -- |
| Minnesota | (Inactive) | -- | -- |

Other

National Cancer Institute, Experimental Drug Investigator #14504 (1988-1997)
Cancer and Leukemia Group B (CALGB) member (1988-1993)

PROFESSIONAL APPOINTMENTS

| | |
|-----------------|--|
| 11/04 – present | Chief Medical Officer, TolerRx, Inc. 300 Technology Square Cambridge, MA 02139 Reporting to: D. Ringler, CEO |
| 7/02-11/04 | Vice President and Head, Clinical Development and Medical Affairs TolerRx, Inc. 300 Technology Square Cambridge, MA 02139 |

Reporting to: D. Ringler, CEO

- 7/01-7/26/02 Senior Vice President, Medical Affairs and R&D
Sepracor Inc.
84 Waterford Drive Marlborough, MA 01752
Reporting to: P. Rubin, Exec VP R&D and J. O'Shea President and COO
Products: Xopenex (beta-agonist) Inhalation Solution; Xopenex MDI;
Lunesta (sedative hypnotic; Estorra; s-zopiclone); arformoterol (beta
agonist); s-oxybutynin (urinary incontinence).
- 5/01-7/01 Senior Vice President, Medical Operations
Sepracor Inc.
111 Locke Dr. Marlborough, MA 01752
Reporting to: P. Rubin, Executive Vice President, R&D
- 3/98-5/01 Vice President , Medical Operations
Sepracor Inc.
111 Locke Dr. Marlborough, MA 01752
Reporting to: P. Rubin, Executive Vice President, R&D
- 7/97- 3/98 Medical Director, Rebif® Multiple Sclerosis Strategic Bus. Unit (SBU)
Ares-Serono Inc.
100 Longwater Circle, Norwell, MA
Reporting to: J. Mohr, Executive Director Multiple Sclerosis SBU
- 1/96-6/97 Medical Director, Virology/Oncology, R&D
Ares-Serono Inc.
100 Longwater Circle, Norwell, MA
Reporting to: H. Samra, President of Serono Laboratories and
Senior Executive VP, North American Region
Products: 1. rIFN-beta (Rebif®; Phases 1,2,3 USA and EU)
 2. rIL-6 (Sigosix; Phases 1,2)
- 3/94-1/96 Associate Medical Director, Immunology/Oncology, R&D
Ares-Serono Inc.
100 Longwater Circle, Norwell, MA
Reporting to: H. Samra, President of Serono Laboratories and Senior
Executive VP, North American Region
Products: 1. rIFN-beta (Rebif®; Phases 1,2,3 USA)
 2. rIL-6 (Sigosix; Phases 1,2)
 3. rHu Growth Hormone (Serostim) AIDS Wasting
- 6/93-3/94 Associate Medical Director, Immunology/Oncology R&D
Ares-Serono Inc.
100 Longwater Circle, Norwell, MA
Reporting to: J. Breitmeyer, VP and Medical Director,

Immunology/Oncology R&D
Product: Recombinant human INF-beta (Rebif; Phases 1,2,3 USA)

ACADEMIC APPOINTMENTS

- 2003 – present Visiting Lecturer; Bouve College of Health Sciences; School of Pharmacology, Northeastern University, Boston MA
- 1991 - 1993 Assistant Professor of Medicine, Divisions of Solid Tumor Oncology and Investigational Therapeutics, Department of Medicine, RPCI and SUNY Buffalo, Buffalo, NY.
- 1991 Assistant Professor of Medicine, Divisions of Bone Marrow Transplantation and Hematologic Malignancies, Department of Medicine, RPCI and SUNY Buffalo, Buffalo, NY.
- 1989 - 1993 Assistant Research Professor, Department of Microbiology/Immunology, RPCI and SUNY Buffalo, Buffalo, NY.
- 1988 - 1991 Assistant Professor of Medicine, Division of Clinical Immunology, Department of Medicine, Roswell Park Cancer Institute, and the State University of New York at Buffalo, Buffalo, New York
- 1987 - 1988 Consultant, Iowa Foundation for Medical Care (Quality Assurance), Iowa City, IA.
- 1985 - 1988 Attending and Staff Physician, Medical Service, Oncology Division, Veteran's Administration Medical Center, Iowa City, IA.
- 1985 - 1988 Assistant Professor, Division of Hematology/Oncology, Department of Internal Medicine, University of Iowa College of Medicine, Iowa City, Iowa.
- 1984 - 1985 Staff Physician, Peninsula Industrial Medical Clinic, San Jose, CA
- 1983 - 1985 Staff Physician, Mountain View Community Health Center, Mountain View, California.

DRUG DEVELOPMENT EXPERIENCE

TolerRx, Inc. Cambridge MA (2002- present)

1. TRX4 (aglycosyl anti-CD3) Monoclonal Antibody (autoimmunity)
Preclinical; preIND; IND; Phase I
2. TRX1 (aglycosyl anti-CD4) Monoclonal Antibody (autoimmunity; transplantation)
Preclinical; preIND; IND; Phase Ia; Phase Ib

Sepracor, Inc. Marlborough MA (1998 – 2002)

1. Estorra (s-zopiclone) Sedative – Hypnotic (acute and chronic insomnia)
Preclinical; IND; Phases I, II, III, IV (FDA approved NDA 2004)
2. Xopenex (levalbuterol solution) short acting beta agonist (asthma;COPD)
Preclinical; Phases II, III, IV (FDA approved NDA 1998; sNDA 2002)
3. Xopenex (levalbuterol HFA MDI) short acting beta agonist (asthma;COPD)
Preclinical; Phases I, II, III, (NDA submitted 2004)
4. Arformoterol (RR-formoterol solution) long-acting beta agonist (COPD)
Preclinical; IND; Phases I, II, III (NDA pending submission)
5. Soltara (tecastermizole) antihistamine (seasonal allergies)
Preclinical; IND; Phases I, II, III (FDA non-approvable letter 2002)
6. Esoxybutynin (s-oxybutynin) urinary incontinence
Preclinical; IND; Phases I, II
7. S-amlodipine calcium channel blocker (hypertension)
Preclinical; IND; Phases I, II
8. R-fluoxetine selective neurotransmitter reuptake inhibitor
Preclinical; IND; Phase I (partnered to Lilly)
9. SEP226330 (selective neurotransmitter reuptake inhibitor) (restless legs syndrome)
Preclinical; IND; Phase I
10. Head of Committee that reviewed and approved investigator-initiated preclinical and clinical trials

Ares Serono Inc. Rockland, MA (1993-1998)

1. Rebif (beta interferon) immunosuppressive/immunomodulator (multiple sclerosis; hepatitis C; malignant gliomas; colon cancer; genital warts)
Phases I, II, III, IV (EMEA approval 1998; FDA approved 2002 for MS)
2. Sigosix (rhuman Interleukin 6) stem cell growth factor (bone marrow failure states; thrombocytopenia after radiation/chemotherapy)
Phases I, II (product development discontinued after Phase II)
3. Serostim (rhuman growth factor) (AIDS wasting)
Phases II, III (FDA approved 1996; EMEA orphan status 2000; negative opinion for full approval 2003)

PROFESSIONAL AND ACADEMIC HONORS

Tri-Beta Biological Honor Society, 1974
National Research Service Award, 1977-1979
Vere Wenger Travel Award for Cancer Research, 1987
Fellowship, American College of Physicians (FACP 1992)

ORGANIZATIONAL MEMBERSHIPS AND OFFICES HELD

Societies:

American Society of Clinical Oncology (ASCO)
American Society of Hematology (ASH)
American College of Physicians (ACP)
Drug Information Association (DIA)
Mayo Alumni Society

COMMUNITY/FACULTY/DEPARTMENTAL SERVICES

Community:

Chairman, Braunview Homeowner's Association Safety Committee (1990-1992).
Overseer, South Shore Conservatory of Music Governing Board, Hingham, MA
(1994 - present)
Physicians for Human Rights USA (PHRUSA) (2001 – present)

University Service:

1. Grant reviewer for VAMC (Immunology/Cancer Biology) (1988-1994).
2. Ad hoc manuscript reviewer (1983-1998):
 - Cancer Research
 - Blood
 - Clinical Immunology and Immunopathology
 - Journal of Interferon Research
 - Annals of Otology, Rhinology and Laryngology
 - The Cancer Journal (Villejuif, France)
 - Journal of Leukocyte Biology
 - Cancer Immunology and Immunotherapy
 - Southern Medical Journal

PROFESSIONAL DEVELOPMENT AND CONTINUING EDUCATION:

FDA Experience (up to 1997)

1. Advisory Committee Meeting - Cephalon Myotrophin Approval in Amyotrophic Lateral Sclerosis. Bethesda, MD. May 8, 1997.
2. Advisory Committee Meeting - Guilford Pharmaceuticals Gliadel Wafer Approval in Resected Malignant Glioma. June 14, 1996. Bethesda, MD.
3. Advisory Committee Meeting - Upjohn Irinotecan Accelerated Approval in Colorectal Cancer. June 13, 1996. Bethesda, MD.
4. Pre-BLA Meeting - Sero Rebif BLA in Condyloma Accuminata. Bethesda, MD. December 10, 1996 (Presented and discussed results of 1 Phase II and 3 Phase 3 clinical trials to CBER).
5. End-of-Phase II Meeting - Sero Rebif in Colorectal Cancer. Bethesda, MD. December 5, 1996. (Presented and discussed proposed Phase III protocol to CBER/CDER committee).
6. Advisory Committee Meeting - Sero Serostim Approval in AIDS Wasting. Bethesda, MD. March 15, 1996.
7. Mock Advisory Committee for Sero Serostim in AIDS Wasting. December 20, 1995. Plymouth, MA.
7. Advisory Committee Meeting - Biogen Avonex Approval in Multiple Sclerosis. Bethesda, MD. December 4, 1995.
8. "Preparing for an FDA Clinical Audit" Sero Laboratories, Inc. In-House Training Course. January 16-17, 1995.
9. "The Food, Drug and Cosmetic Act and Its Implementing Regulations Related to Pharmaceutical Marketing" by Thomas Scarlett, Esq. Former Chief Counsel of the FDA. Sero Labs, Inc. Norwell, September 28, 1994.
10. FDA CBER Biologic Response Modifiers Advisory Committee Meeting, Bethesda, Maryland. May 25-26, 1994.

Management Training (up to 1997)

- "Targeted Candidate Selection and Interviewing" Management Skills Seminar. Braintree, MA. June 12, 1997.
- "Common Decency in the Workplace" Learning Dynamics, Inc. Seminar. Braintree, MA. April 30, 1997.

“Building Market-Focused Organizations”. Lanning , Phillips and Associates. Babson College Executive Training Center, Babson Park, MA. April 14-16, 1997.

“Design and measurement of quality of life outcomes in clinical trials and product promotion”. Dr. J. Ware. Norwell, MA. January 6, 1997.

Goal Setting & Development Planning. Outsourcing Solutions, Inc. Braintree, Massachusetts. March 22, 1996.

Performance Management Workshop. Strategic Outsourcing, Inc., Braintree, MA. November 28, 1995.

Computer Skills Training (up to 1997)

Advanced Excel (Professional Devel. Group (PDG). Braintree, MA. June 18-19, 1997.

Using the Internet in Business Skillpath Inc. May 9, 1996.

Lotus Notes Introduction (PDG) 1996.

Beginnning and Intermediate Word (PDG) 1994.

Beginning and Intermediate Excel (PDG) 1994.

Introduction to Powerpoint (PDG) 1995.

Introduction to Microsoft Project (PDG) 1996.

Introduction to Windows Seminar (PDG) 1994.

Formal Business Development and Education (up to 1997):

MBA Evening Program, Frank Olin School of Business, Babson College, Babson Park, MA. Matriculating Student.

- Summer Session I 1997. Organizational Behavior (Grade: A-).
- Winter Session 1997. Managerial Aspects of Accounting (Grade: A-).
- Fall Session 1996. Financial Accounting. (Grade: B+).

MBA Program, University of Massachusetts Graduate School of Business Administration. Boston, MA. Non-matriculating student.

- Fall Session 1995. Marketing for Managers (Grade: A).
- Summer Session 1995. Accounting for Managers (Grade: A).

Undergraduate Business Program, University of Massachusetts. Boston, MA.

- Winter Semester 1995. Introduction to Business Management (Grade: A).

Courses, Meetings and Seminars (up to 1997):

United States Rebif Multiple Sclerosis Advisory Board, Chicago, IL. October 25 - 26, 1997

Market Research Interviews. Biotext International . Brigham and Women's Hospital Dept. of Neurology. Boston, MA. October 14, 1997.

American Neurological Association 122nd Annual Meeting and ACTRIMS (Americas Committee for Treatment and Research in Multiple Sclerosis) 2nd Annual Symposium. San Diego, CA. September 28 - October 1, 1997

World Congress of Neurology Annual Meeting. Buenos Aires, Argentina. September 15-21, 1997.

"Multiple Sclerosis - Continued Drug Discovery and Comprehensive Clinical Trials Update". IBC's 5th Annual Conference on Multiple Sclerosis. Cambridge, MA. June 16-17, 1997.

University of Maryland Rebif in Colorectal Cancer Seminar. Baltimore, MD. July 17, 1997.

ASCO 33rd Annual Meeting, Denver, CO, May 17-20, 1997.

NIH Consensus Development Conference on Management of Hepatitis C. Bethesda, MD. March 24-26, 1997.

Ares-Serono Multiple Sclerosis SIM. Geneva, Switzerland. March 18-19, 1997

GF 8468 Study Coordinator's Meeting. Sarasota, FL. February 14-17, 1997.

Ares-Serono Hepatitis C GF 9142 investigator's meeting. Geneva, Switzerland. February 24-25, 1997

Ares-Serono Colorectal Cancer GF 8468 investigator's meeting. Geneva, Switzerland. January 20, 1997.

ASCO 32nd Annual Meeting. Philadelphia, PA. May 18-21, 1996.

IBC's Annual Industry Congress-Hepatitis, Washington, D.C. March 14-15, 1996.

Serono's Hepatitis C Investigator's Meeting, Chicago, Illinois. February 28, 1996.

American Academy of Dermatology 54th Annual Meeting, Washington, D.C.
February 10-15, 1996.

Thrombopoiesis in Clinical Medicine, Update 1995, Seattle, Washington.
December 1, 1995.

ASH 37th Annual Meeting, Seattle, Washington. December 1-4, 1995.

American Association for the Study of Liver Diseases 46th Annual Meeting,
Chicago, Illinois. November 4-7, 1995.

“Advances in the Understanding and Treatment of Multiple Sclerosis”, International
Business Communications Seminar. Cambridge, MA. May 22-24, 1995.

ASCO 31st Annual Meeting, Dallas, Texas. May 20-22, 1995.

“AIDS Wasting” by Dr. Marc Hellerstein. University of California at San Francisco,
Serono Laboratories, Inc. April 12, 1995.

ASH 36th Annual Meeting, Nashville, Tennessee. December 3-6, 1994.

American Association for the Study of Liver Diseases 45th Annual Meeting,
Chicago, Illinois. November 12-15, 1994.

Society for Biological Therapy 8th Annual Meeting, Napa Valley, California.
October 27-30, 1994.

Drug Information Association Meeting “Case Report Form Methods, Standards,
Design and Technical Solutions”, Arlington, Virginia. August 29-30, 1994.

Serono Symposium, “Interferons and Interacting Cytokines: Cellular and Clinical
Response and Resistance”, Litchfield Park, Arizona. June 23-26, 1994.

ASCO 30th Annual Meeting, Dallas, Texas. May 14-17, 1994

Radiation Therapy Oncology Group (RTOG) Meeting, Houston, Texas.
February 17-20, 1994.

Serono IL-6 Investigator’s Meeting, Toyko, Japan. January 20-24, 1994.

ASH 35th Annual Meeting, St. Louis, Missouri. December 3-7, 1993.

Harvard Medical School Review Course “Cancer Medicine”, Boston, MA.
October 4-8, 1993.

Serono Symposium, “Platelets and Cellular Support in Clinical Oncology”,
Arlington, Virginia. September 30-October 2, 1993.

RTOG Meetings, Philadelphia, Pennsylvania. July 23-25, 1993.

Teaching, Other Committees, and University Appointments (up to 1998):

1. Scientific Review Committee (Ad hoc member), RPCI, 1989-1993.
2. Staff Seminar Committee, RPCI, 1989-1993.
3. Coordinator, RPCI Department of Medicine Research Conferences, 1989-1992.
4. Critical Care Committee, RPCI, 1990-1992.
5. Utilization Review Committee, 1990-1992.
6. Nuclear Medicine Search Committee, 1990-1992.
7. Young Investigator Advisory Counsel, 1989-1993.
8. Co-chairman, Cytokine Development Committee of RPCI, 1991-1992.
9. Ad hoc reviewer, NIH General Medicine B Study Section SBIR Proposals (December, 1991).
10. Radiation Safety Committee, RPCI, 1991-1993.
11. Phase I/II Clinical Research Committee, RPCI, 1991-1993.
12. Ad hoc reviewer, Institutional Review Board (RPCI), 1992-1993.
13. Roswell Park Cancer Institute Medical Ground Rounds Coordinator, 1992-1993.
14. Coordinator, Solid Tumor Clinicopathology Conference, 1992-1993.
15. Coordinator, Sarcoma/Melanoma Weekly Multidisciplinary Conference, 1992-1993.
16. Medical Oncology Faculty Liaison, Solid Tumor Chemotherapy Day Unit, 1992-1993.
17. Physician representative, Sero Task Force on Blood-Borne Pathogens in the Workplace 1994-1998).

COURSES TAUGHT AND OTHER TEACHING ACTIVITIES

Classroom, Seminar or Teaching Laboratory:

Year

- 1986 - 1988 Hematology/Oncology Fellows Core Curriculum, Lecturer.
- 1989 - House Staff Introduction to Oncology, RPCI.
- 1989 - Microbiology 501-502, RPCI.
- 1990 - Molecular and Cellular Biology (BIR/MIR 530), RPCI.
- 1991 - Cellular and Molecular Immunology (Micro 609), Department of
Microbiology/Immunology, SUNY Buffalo.
- 1992 - PHM-512 Pharmacotherapeutics SUNY Buffalo "Biotech Approaches to
Cancer."
- 1992 - SUNY Buffalo First year Medical Student's Cancer Selective Course:
Solid Tumor Malignancies: Biologic and Clinical Considerations"
(February) (Overall student rating 4.8 out of 5 - excellent).
- 1992 - Coordinator and Lecturer, Oncology Nurse Educational Seminar,
12/14/92, RPCI.
- 1993 - Nurse Oncology Course, "Chemotherapeutic Agents, Toxicities, and
Adjunctive Treatments", 1/12/93 at RPCI.
- 1993 - SUNY Buffalo Pharmacy-512 Pharmacotherapeutics (1/18/93),
"Biologic Response Modifiers in Oncology".
- 1993 - SUNY Buffalo Internal Medicine Board Review Conference Series at
Buffalo General Hospital (1/20/93) "Medical Oncology Chemotherapy
Overview".

Clinical Teaching (in ward, clinic, or operating room):

Year

1988 - 1993 Roswell Park Cancer Institute:

Attending on Medical Oncology Unit - 3-4 months per year
Attending on Oncology Consulting Service - 2-3 months per year
Supervising Attending, General Oncology Clinic - weekly
Attending, Breast Cancer - weekly (1990-1993)
Attending, Melanoma/Sarcoma Clinic - weekly
Attending, Lung Cancer Clinic - weekly

RESEARCH SUPERVISION

1985 - 1988 University of Iowa:

Ross Bacon, MS (Medical Student Research Elective, 1986-87).

Susan Aquilar, MD (Resident Research Elective, 1987).

K. Whitford, MD (Research Elective, 1986).

D.E. Dawson, MD, MS (Post-doctoral Fellowship, 1986-87).

D. Vesole, Ph.D., MD (Post-doctoral Fellowship - 1987).

V. Jones, MD (Post-doctoral Fellowship, 1987-88).

1988 - 1993 Roswell Park Cancer Institute:

D. Cemerlic, MD (Post-doctoral Fellowship, 1989-90).

J. Genco, MS (Master's Degree - laboratory project, 1989-90).

J. Wilkes, MD (Oncology Fellow's Research Project, 1992-1993).

PAST GRANT SUPPORT (1986 - 1993)

Fellowships/Grants/Clinical Trials:

1. VA Research Advisory Group (RAG) Grant. Principal Investigator. Spring, 1986 (\$29,655).
2. "Antiproliferative Monoclonal Antibodies" Principal Investigator. VA Merit Review Grant. 10/86-10/89, (\$94,882).

3. "A Phase I/II Study of High Dose Continuous Infusion Recombinant Human Interleukin-2 with Non-Small Cell Lung Cancer and Resistant Lymphoma". Co-investigator. Hoffmann La Roche, Inc. 10/1/88-9/30/89, (\$50,000 total direct cost).
4. "A Phase I/II Clinical Investigation to Evaluate the Safety and Efficacy of Continuous Infusions of Recombinant Interleukin-2 and Phenylalanine Methyl Ester Pretreated Cells in Patients with Unresectable and/or Metastatic Melanoma and Renal Cell Cancer". Co-Investigator. Dupont Corporation. 1/1/89-12/31/90, (\$270,000 total direct cost).
5. "Therapy of Renal Cell Carcinoma and Malignant Melanoma with Interleukin-2", Co-Investigator. Hoffmann La Roche, Inc. 6/1/90-5/31/91, (\$39,000 total direct cost).
6. ACS Institutional Research Grant (RPCI). Principal Investigator. 10/88-5/89, (\$8,500).
7. "Cytokine Influence on ADCC". Principal Investigator. Biomedical Research Support Grant.
8. "Characterization of Human Fc Receptors by Multiparameter Three-Color Flow Cytometry". Principal Investigator. Flow Cytometry Applications (RPCI), 11/90-10/91, (\$1,800).
9. "Anti-idiotypic Therapy for Recurrent B-Cell Lymphoma". Principal Investigator. IDEC Pharmaceuticals. 1989-1991 (\$12,060, total direct cost).
10. "Recombinant Human Erythropoietin for Chemotherapy-Induced Anemias". Principal Investigator. Chugai-Upjohn. 1991-1992, (\$26,964 total costs).
11. "Phase I Immunopharmacologic Study of Linomide in Patients with Malignant Disease". Principal Investigator (RPCI #DS 91-02). 1991-1992, (\$82,519 total costs).
12. "Phase III Trial of Rhu GM-CSF in Patients with Febrile Neutropenia Following Cancer Chemotherapy". Principal Investigator. Immunex Corporation #9116 (RPCI DS #92-34). Activated 12/92, (\$123,000, total cost).
13. "Phase II Feasibility Study of GM-CSF Priming to Prevent Postoperative Infectious Complications in High-Risk Oncologic Surgery". Principal Investigator. Immunex Research Corporation. (Pilot Phase approved \$10,000).

14. "Phase II Randomized Study of Parental Etoposide and Etoposide Phosphate for the Treatment of Small Cell Lung Cancer" (RPCI #DS 92-19). Principal Investigator. Bristol-Meyers Squibb Protocol CA136-011. 1992-1993, \$20,000 total cost).
15. "Phase I Feasibility Study of Anti-Idiotypic Monoclonal Antibody Vaccine Therapy for Patients with Cutaneous T-Cell Lymphomas" (RPCI #DS 88-22). Principal Investigator. 1991-1993.
16. "Intergroup Post-Operative Adjuvant Alpha-2b(Intron A) in Resected, High-Risk Primary and Regionally Metastatic Melanoma" (CALGB 9190). Co-Principal Investigator. 1992-1993.
17. "Randomized Phase III Trial of Melacine Vaccine vs. Chemotherapy in Patients with Disseminated Malignant Melanoma". Co-Principal Investigator. (Ribi Imunochem Research, Inc. Protocol 2885-12) (RPCI #DS 91-35), 1992-1993.
18. "Neoadjuvant Chemotherapy for Inoperable Non-Small Cell Lung Carcinoma Due to Locally Far-Advanced Disease" (RPCI #DS 87-23). Investigator. 1987-1993.
19. "Dose Intensification of Multiagent Chemotherapy (PACCO) for Stage III Non-Small Cell Lung Cancer - Role of GM-CSF Priming and Prophylaxis". Co-Principal Investigator. (RPCI).
20. "Extended Low-Dose Interleukin-2 Therapy: A Phase I Study of Subcutaneous Administration". Co-Principal Investigator. Cetus Corporation (RPCI #DS 92-36). 1992-1993.

BIBLIOGRAPHY

Peer-reviewed journals

1. Vaickus L, and Tomasi T B. Murine autogeneic mixed lymphocyte reaction. Transplantation, 31:409-416, 1981.
2. Vaickus L, and Letendre L. Pericarditis induced by high-dose cytarabine therapy. Arch. Intern. Med. 144:1868-1869, 1984.
3. Vaickus L, and Levy R. Anti-proliferative monoclonal antibodies: Detection and initial characterization. J. Immunol. 135(3): 1987-1997, 1985.
4. Vaickus L, Robinson M, and Lynch R G. Analysis of human peripheral blood mononuclear cells bearing Fc receptors for the three major immunoglobulin isotypes. Clin. Immunol. Immunopath. 47:106-119, 1988.

5. **Vaickus L**, Jones V, Morton C, Whitford K and Bacon R. Antiproliferative mechanism of anti-class II monoclonal antibodies. *Cell. Immunol.* 119:445-458, 1989.
6. Dawson D E, Sekhar V, Pearson G, and **Vaickus L**. Nuclear magnetic resonance spectroscopy of plasma for the detection of head and neck cancer. *Am. J. Otolaryngology.* 10:244-249, 1989.
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Non-Refereed Journals

1. Davis R and **Vaickus L**. Antibiotic therapy in the febrile neutropenic patients. Iowa Cancer Letter, 6(4):3, 1987.
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4. **Vaickus L** and Foon K A. Clinical applications of monoclonal antibodies in oncology. Hospital Formulary. The P & TG Committee Journal, 25, No.1, pp.50-56, 1990.
5. **Vaickus L** and Foon K A. Clinical Immunology at Roswell Park Cancer Institute - Biotherapy of Cancer. Editorial. Oncoline. March, 1990.
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10. **Vaickus L** and Breitmeyer J. Interferon plus Tamoxifen Treatment for Advanced Breast Cancer: In vivo biologic effects of two growth modulators. Breast Diseases Yearbook Quarterly Review. Editorial. 5: 76, 1994 (March).
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12. **Vaickus L**, and J. Breitmeyer. "Interferon plus tamoxifen treatment for advanced breast cancer: in vivo biologic effects of two growth modulators. Commentary. Breast Diseases: A Year Book Quarterly. Volume 5; 1: 76. 1994.

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14. Handley D, Morley J, **Vaickus L**. Levalbuterol hydrochloride. *Exp. Opin. Invest. Drugs* 12:2027-2041. 1998.
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Books and Book Chapters

1. Lynch R G, Chang Y, Mathur A, Robinson M, **Vaickus L**, and Mueller A. Therapeutic implications of immunoregulatory circuits in malignant monoclonal gammopathies. *EURAGE: Monoclonal gammopathies II-Clinical significance and basic mechanisms*. J. Radl and B van Camp (eds.) pp 69-75, 1989.
2. **Vaickus L**. and Foon K A. Biological therapies of lymphomas. In: *Malignant Lymphoma: Biology, Diagnosis and Treatment*. C W Erber, S Flecknoe-Brown and M. Garson, eds: Harwood Academic Publications, Chapter 11 p. 1777-195, 1990 (December).
3. **Vaickus L**, and Foon K A. Immunobiology of acute leukemia. *Neoplastic Diseases of the Blood*. Wiernik P H, Canellos G P, Kyle R A, and Schiffer C A. 2nd Ed. Churchill-Livingstone, NY. Pp. 183-214, 1991 (May).
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5. **Vaickus L**, Ball E D, and Foon K A. "Immunologic classification of leukemia". *Clinical Cancer Markers: Diagnosis, Prognosis and Monitoring*. Humana Press, S. Sell, editor. 1992.

Abstracts (* = Oral or poster presentation)

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2. ***Vaickus L**, and Levy R. Anti-Proliferative Monoclonal Antibody That Inhibits Cytokinesis. (Accepted for Mini-Symposium presentation). *Fed. Proc.* 44(4):1178, 1985.
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6. Vaickus L, Robinson M, and Lynch R G. Analysis of Human Peripheral Blood Mononuclear (PBMC) and Purified T Cells Possessing Fc Receptors (FcR) for the Major Immunoglobulin Subclasses. Blood, 68 (#5, Suppl. 1). 1986.
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10. Vaickus L, Morton C, Whitford K, and Bacon R. Characterization of the Antiproliferative Effect of Anti-HLA-DR MABs on Human Cell Lines of Different Lineages. Midwest Regional APCR Meeting, Clin. Res., 35(6), 1987.
11. *Dawson D E, Sehkar V, and Vaickus L. Human Tumor Specific Monoclonal Antibodies Made by Different Tolerization-Immunization Strategies. (Poster). Midwest Regional APCR Meeting, Clin. Res., 35(6), 1987.
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14. *Dawson D E, Sehkar V, Pearson G, and Vaickus L. Nuclear Magnetic Resonance Spectroscopy of Plasma for the Detection of Head and Neck Cancer. Second International Conference on Head and Neck Cancer. Boston, MA. August 1988.
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33. *Meropol N J, Porter M, Perez R P, **Vaickus L**, Loewen G M, Creaven P J, Wilkes K A, Caligiuri M A. Low Dose Interleukin-2 (IL-2): Daily Subcutaneous Injection Results in Selective In Vivo Expansion of Natural Killer (NK) Cells with Minimal Toxicity. ASCO Proceedings 13:296 (A965) (March 1994).
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35. Byhardt R, Wilson J F, Lawton C, Witt, P L, Borden E, **#Vaickus L**, **#Breitmeyer J**, *Chang, A Y. Med. Coll of Wisconsin, Milwaukee, WI 53226, **#Serono Labs Inc.**, Norwell, MA 02061 and *Genesee Hosp., U. Of Rochester, Rochester, NY 14642. Phase I Trial of Recombinant β -Interferon (r-IFN β , R-FRONE $\text{\textcircled{R}}$,) and Radiation Therapy (RT) for Non-Small Cell Lung Cancer (NSCLC). ASCO Proceedings 13:355 (A1189) (March 1994).
36. *Byhardt R, Wilson JF, Lawton C, Witt PL, Borden E, **Vaickus L**, Breitmeyer J, Chang, AY. Phase I Trial of Recombinant β -Interferon (r-IFN β , R-FRONE $\text{\textcircled{R}}$,)

and Radiation Therapy (RT) for Non-Small Cell Lung Cancer (NSCLC). (7th World Congress on Lung Cancer, 1994).

37. Yung WKA, Levin VA, Kyritsis A, Jaeckle K, Vaickus L, and Peterson P. A Phase II Study of rIFN-beta +/- cRA in Recurrent Gliomas. Soc Biol Therapy, 1994.
38. Hong YK, Steck PA, Vaickus L, Yung WKA. Modulation of VEGF and EGFR Expression by Recombinant IFN-beta and Dexamethasone in Human Glioma Cells. (American Association of Cancer Research, 1995).
39. Yung WKA, Levin VA, Kyritsis A, Jaeckle K, Winn R, Baidas S, Martuza R, and Vaickus L. Phase II Study of rh-IFN-beta +/- cRA in Recurrent Gliomas. (Proceedings of the American Society of Clinical Oncology, 1995).
40. de Alarcon PA and Vaickus, L. Glycosylated recombinant human Interleukin-6 (r-hIL-6) (Sigosix) in the treatment of the thrombocytopenia and absent radii (TAR) syndrome. (American Society of Pediatric Hematology/Oncology, 1997).
41. Busse WW, Greos L and Vaickus L. Lower doses of Xopenex (levalbuterol) are as effective as racemic albuterol in the prevention of exercise induced bronchospasm (EIB). J Allerg and Clin Immunol. 103: S135. 1999.
42. Pleskow W, Nelson H, Kemp J, Vaickus L. Improved secondary efficacy endpoints with levalbuterol (Xopenex) vs racemic albuterol [abstract]. American College of Allergy, Asthma, and Immunology. Philadelphia, PA, 1998:35.
43. Gumbhir-Shah K, Koch P, Jusko W, Vaickus L. Consecutive doses of levalbuterol and racemic albuterol result in comparable safety and efficacy: a PK and PD study in mild-moderate asthmatics [abstract]. *Annals of Emergency Medicine* 1999;34:S55.
44. Day J, Briscoe M, Rafeiro E, DeGraw S, Clancy J, Taylor A, Jarlenski D, Reasner D, Vaickus L. Norastemizole acts earlier and is more effective for allergic rhinitis symptoms than loratadine and placebo in an allergen challenge system [abstract]. *Journal of Allergy and Clinical Immunology* 2000;105:S202.
45. Nowak R, Emerman C, Schaefer K, Vaickus L. A Pilot Study to Determine the Safety and Efficacy of Escalating Doses of Levalbuterol in the Treatment of Acute Asthma in the Emergency Department (ED) [abstract]. *Academic Emergency Medicine* 2000;7:433.
46. Colice G, Vaickus L. Second hand (S)-albuterol: RT exposure risk after racemic albuterol [abstract]. *Annals of Allergy, Asthma, & Immunology* 2002;88:132.
47. Vaickus L, Schaefer K, Claus R. Impact of decreasing doses of racemic albuterol and levalbuterol on efficacy: a pooled analysis [abstract]. *Journal of Allergy and*

Clinical Immunology 2002;109:S233.

48. Ferguson C, DeGraw S, Wilson A, Tripp K, and **Vaickus L**. Human Cardiac Safety of Tecastemizole: No Evidence of QT Prolongation Despite High Plasma Concentrations [abstract]. *Annals of Allergy, Asthma and Immunology* 2001; 86: ACAAI-49422.
49. Ng C, Wu B, Fielder P, and **Vaickus L**. Pharmacokinetic/Pharmacodynamic Modeling of Anti-CD4 Monoclonal Antibody (TRX1) in Healthy Male Volunteers. American College of Clinical Pharmacology (submitted; May 2004).
50. Winsor-Hines D, Carmody F, Ching S, **Vaickus L**, and Ponath P. Tolerance Induction to Human Factor VIII with an Anti-CD4 Antibody in Mice with High Titer Inhibitors. Clinical Investigative Medicine 12th International Congress of Immunology/FOCIS, July 18-23rd 2004, Montreal CA

MANUSCRIPTS SUBMITTED OR IN PREPARATION

1. None

Talks, Seminars, Grand Rounds, etc. (up to 1993)

1. 1984 "Paroxysmal Nocturnal Hemoglobinuria" Stanford University Hematology Journal Club.
2. 1985 "Leukemia: Diagnosis and Therapy" Stanford University, conference for Heme/Onc. Practitioners.
3. 10/25/86 University of Iowa Resident's Conference: "Autoimmune Neutropenia".
4. 11/16/86 CME, Cancer Teaching Day: "Clinical Application of Monoclonal Antibodies".
5. 1/02/86 Grand Rounds: "NK Cell Leukemia".
6. 2/05/86 Hematology/Oncology Journal Club.
7. 5/14/86 Oncology Nursing Conference for Advanced Practitioners: "Medical Management of Aggressive Lymphomas".
8. 6/02/86 State of the Art Lecture: "Chronic Leukemias".
9. 6/20/86 Hematology Research Conference.

10. 7/24/86 Grand Rounds: "Adult Immunodeficiency Exclusive of AIDS".
11. 11/25/86 Immunology Group Seminar: "Antiproliferative Effects of Anti-HLA DR MAB on Human Cell Lines".
12. 1/30/87 Research in Progress: "Antiproliferative Effect of Anti-HLA DR MABs on Human Cells".
13. 4/07/87 Heme/Onc Grand Rounds: "MRI in Hematologic Malignancies".
14. 4/14/87 Resident's Conference: "Macrocytosis".
15. 4/17/87 Heme/Onc Journal Club: "Cell Activation Mechanisms".
16. 11/19/87 Dept. Of Int. Med. Research Conference on: "Anti-proliferative Mechanism of Anti-HLA DR MABs".
17. 1/07/88 Medical Grand Rounds: "Post-transplantation Lymphoma".
18. 1/20/88 Heme/Onc Journal Club.
19. 3/15/88 Heme/Onc Journal Club.
20. 3/02/89 RPCI Lab Research Conference: "Antitumor Mechanisms of Lym-1".
21. 8/25/89 Grand Rounds, RPCI, "Plasma Cell Dyscrasias".
22. 12/13/89 Cytokine Effect on Lym-1 Antitumor Mechanisms". Invited speaker, Lederle Laboratories, Pearl River, NY.
23. 9/14/90 "Growth Factors in Oncology" Invited speaker, Fitzpatrick Cancer Center Symposium, Plattsburgh, NY.
24. 11/21/90 RPCI Journal Club: "Clinical Trials with IL-3".
25. 2/05/91 "CD7+ Stem Cell Leukemias", Buffalo General Hospital Hematology Conference.
26. 2/08/91 RPCI Grand Rounds: "Plasma Cell Dyscrasias".
27. 2/20/91 RPCI Divisional Review "Antibodies to HTLV-I and HTLV-II Surface Proteins".
28. 3/18/91 "Antibody Dependent and Independent Cellular Cytotoxicity" Sherman Hall, Rm 223, (Micro 609) SUNY Buffalo Medical Campus.

29. 3/20/91 "Growth Factors (EPO, G-CSF, GM-CSF, IL-3) in Oncology", Children's Hospital, Buffalo, NY.
30. 3/27/91 "Colony Stimulating Factors and Cancer", Buffalo General Hospital.
31. 3/28/91 Clinical Protocols Conference: Phase I/II Trial of Erythropoietin for Anemia Associated with Cancer Chemotherapy.
32. 5/01/91 "Clinical Use of Myeloid CSFs", Brooks Memorial Hospital, Dunkirk, NY.
33. 6/19/91 "Recombinant Growth Factors in Oncology" Genesee Memorial Hospital, Grand Rounds, Batavia, NY.
34. 6/20/91 "Recombinant Growth Factors in Oncology" Our Lady of Lourdes Hospital, Grand Rounds, Binghamton, NY.
35. 8/01/91 "Hematopoietic Regulators" Center for Cancer Treatment and Research, University of South Carolina. Richland Memorial Hospital, Columbia, SC.
36. 9/20/91 "Diagnosis and Treatment of Multiple Myeloma" and "Review of Growth Factors in Oncology" and "Interesting Case Presentations" (by faculty). Visiting Professor, Williamsport Hospital and Medical Center, Williamsport, PA.
37. 9/21/91 "Monoclonal Antibody Studies in Lymphoma". University of Rochester - RPCI Collaborative Meeting, Batavia, NY.
38. 9/24/91 "Diagnosis, Evaluation, Treatment and Complications of Cancer - Case Reports". Glaxo Pharmaceuticals Preceptorship Training, Roswell Park Cancer Institute, Buffalo, NY.
39. 9/25/91 "Growth Factors and Influence on Tumor Growth" Grand Rounds. W.C.A. Hospital, Jamestown, NY.
40. 10/10/91 "Hematopoietic Regulators - Expanding Role in Oncology" Cancer Nursing Update, Roswell Park Cancer Institute, Buffalo, NY.
41. 1/22/92 "Clinical Role of Colony-Stimulating Factors", Grand Rounds, SUNY Upstate Medical Center (host B. Poiesz), Syracuse, NY.
42. 3/11/92 "Novel Uses of G-CSF and GM-CSF" Gundersen Clinic, LaCrosse, WI.

43. 4/28/92 "The Human Body" Presentation and Discussion to 3rd Grade Class, South Davis Elementary School, Orchard Park, NY.
44. 5/06/92 "Antimetabolites, Alkylating Agents and Plant Alkaloids" Chemotherapy Course for Nurse Oncologists, Roswell Park Cancer Institute, Buffalo, NY.
45. 6/24/92 "Myeloid CSFs - Role in Oncology" H. Lee Moffitt Cancer Center, Tampa, FL.
46. 8/14/92 "Growth Factors for Blood Cell Production". Chataqua Institute, Chataqua, NY (For the National Cancer Society).
47. 9/17/92 "Colony-Stimulating Factors in Ovarian Cancer". Gynecologic Oncology Research Seminar, Roswell Park Cancer Institute, Buffalo, NY.
48. 10/07/92 "Role of Myeloid CSFs in Oncology and Medicine". D.C. General Hospital, Washington, DC.
49. 10/27/92 "Melanoma Update and Review". Community Physician's Open House, Roswell Park Cancer Institute, Buffalo, NY.
50. 11/24/92 "Role of Metastasectomy in Adult Soft Tissue Sarcoma". Faculty Advisor for Oncology Fellows' Combined Medical-Surgical "Pro/Con" Conference, RPCI.
51. 1/26/93 "Prophylactic Lymph Node Dissection in Cutaneous Melanoma". Faculty Advisor for Oncology Fellows' Combined Medical-Surgical "Pro/Con" Conference, RPCI.
52. 2/01/93 "High Dose Chemotherapy with CSF Support for NSCLC". Thoracic Oncology Protocol/New Patient Conference, RPCI.
53. 2/10/93 "Myeloid Colony-Stimulating Factors in Oncology and Medicine - New Applications at Roswell Park Cancer Institute". Invited Grand Rounds Speaker, Eastern Virginia Medical School, Norfolk, VA.
54. 3/02/93 "G-CSF and GM-CSF". Internal Medicine Lecture Series, Department of Medicine Core Lectures, Millard Fillmore Hospital and SUNY Buffalo, Buffalo, NY.
55. 4/05/93 "Melanoma: Diagnosis, Staging, and Therapy". Medical Oncology Case Presentation Conference, RPCI.
56. 5/19/93 Visiting Professor for 1993 Bongiorno Day Memorial Lecture; Long Island College Hospital, Brooklyn, NY.